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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,368	01/12/2005	Charles C Hart	3438-USP-PCT-US	2254

21378 7590 04/11/2007
APPLIED MEDICAL RESOURCES CORPORATION
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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/521,368	Applicant(s) HART ET AL.	
	Examiner Michael G. Bogart	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12 January 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

The declaration lists Raffi S. Pinedjian as an inventor, but that inventor's signature does not appear in the declaration.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.

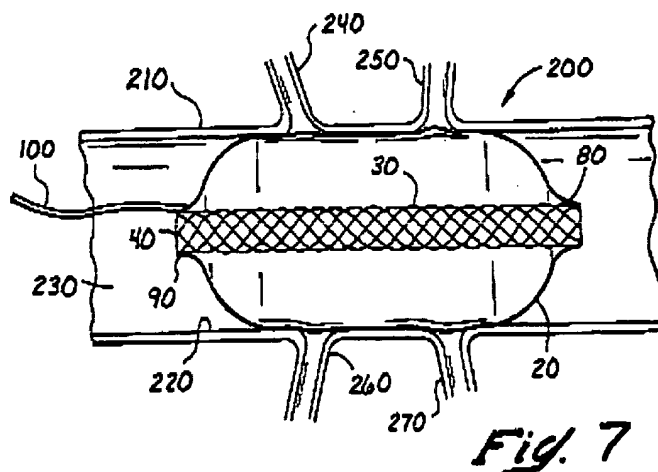
Claims 1-5 and 7-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hart *et al.* (US 6,183,492 B1; hereinafter: "Hart").

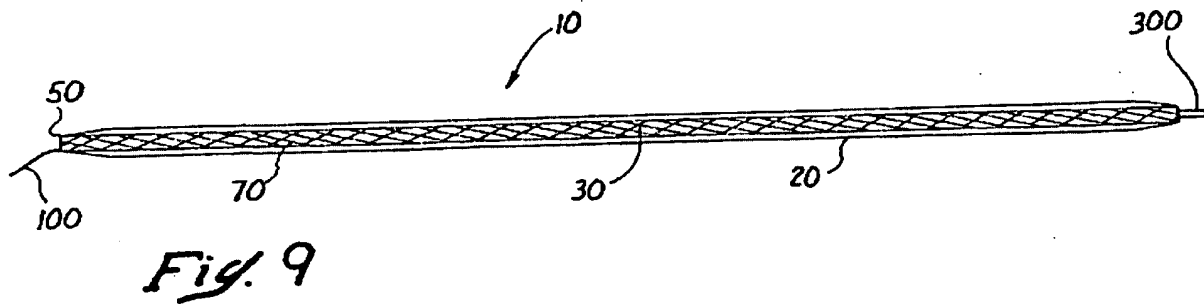
Regarding claim 1, Hart teaches a drainage catheter (10) capable of draining fluid from a body cavity (200) through a body conduit (230), comprising:

an elongate tube having a proximal end and a distal end, and being sized and configured for insertion into the body cavity (200);

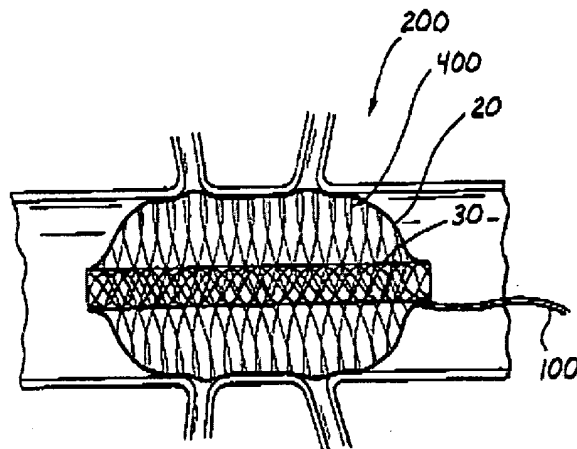
an expandable retention member (20, 72) disposed at the distal end of the elongate tube (30) and being adapted for movement between a low-profile state facilitating insertion of the catheter (10) into the body cavity (200), and an expanded high-profile state facilitating retention of the distal end of the catheter (10) in the body cavity (200); and

a stylet (300) removably insertable into the elongate tube (30) so as to be able to facilitate insertion and placement of the catheter (10) in the body cavity (200)(col. 4, line 31-col. 5, line 46)(see figures 7 and 9, *infra*).





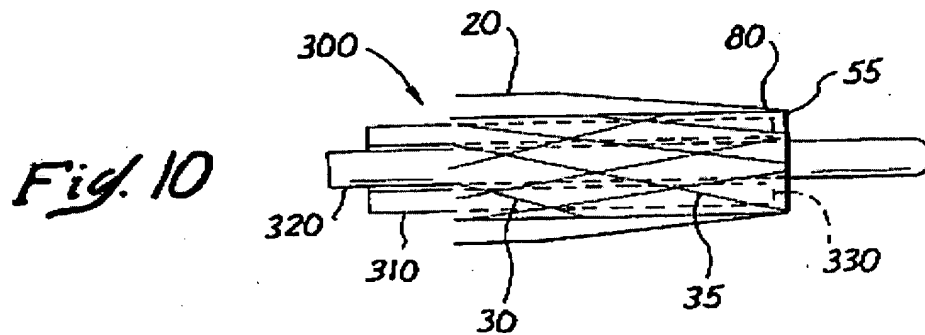
Regarding claims 2 and 3, Hart teaches that the retention member (400) is constructed of woven fabric or mesh (col. 5, lines 47-57)(see figure 17, infra).



Regarding claims 4, 5 and 7 Hart teaches a removable handle (300)(manually graspable element) and a hub (330) receiving the same (col. 4, line 52-col. 5, line 10)(see fig. 10, infra).

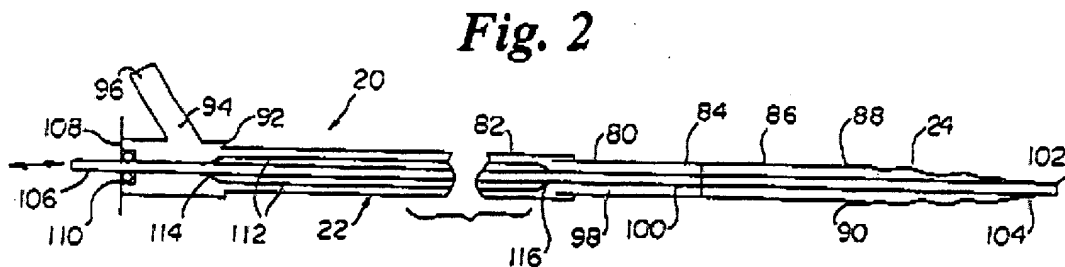
Regarding claim 8, Hart teaches a straight stylet (300)(see fig. 9).

Regarding claim 9, Hart teaches an inflation tube (100)(see fig. 7).



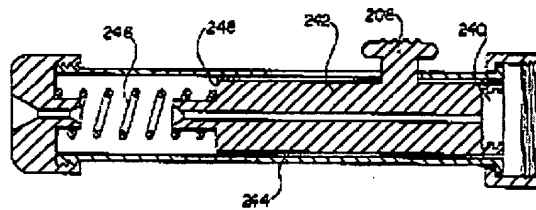
Claims 15, 16 and 18-20 are rejected under 35 U.S.C. § 102(e) as being anticipated by Mickley *et al.* (US 6,264,630 B1; hereinafter "Mickley").

Mickey teaches, a drainage catheter comprising an elongate tube (22), an expandable retention member (24) disposed at the distal end of the tube adapted to move between expanded and non-expanded states to facilitate retention and insertion respectively, and an energy storing member (112) at the distal end of the tube to assist the retention member (24) in collapsing (see figure 2, *infra*).



Regarding claims 16 and 18, Mickley teaches metallic wires that have memory (shape retention)(col. 10, lines 53-66).

Regarding claim 19, Mickley teaches a spiral-shaped energy storing member (246)(see figure 5, *infra*).

Fig. 5

Regarding claim 20, Mickley teaches an energy storage (112) member shaped like a bellows.

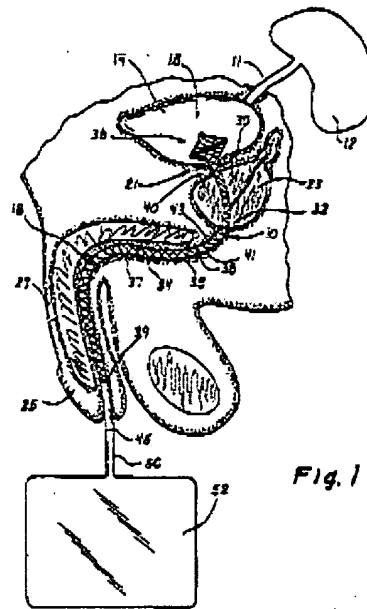
Claims 1, 9, 11 and 12 are rejected under 35 U.S.C. § 102(a) as being anticipated by Pravong *et al.* (CA 2 414 224 A1; hereinafter: "Pravong").

Regarding claim 1, Pravong teaches a drainage catheter (10) capable of draining fluid from a body cavity (15) through a body conduit (18), comprising:

an elongate tube (34) having a proximal end (39) and a distal end (40), and being sized and configured for insertion into the body cavity (15);

an expandable retention member (36) disposed at the distal end (40) of the elongate tube (34) and being adapted for movement between a low-profile state facilitating insertion of the catheter (10) into the body cavity (15), and an expanded high-profile state facilitating retention of the distal end (40) of the catheter (10) in the body cavity (15); and

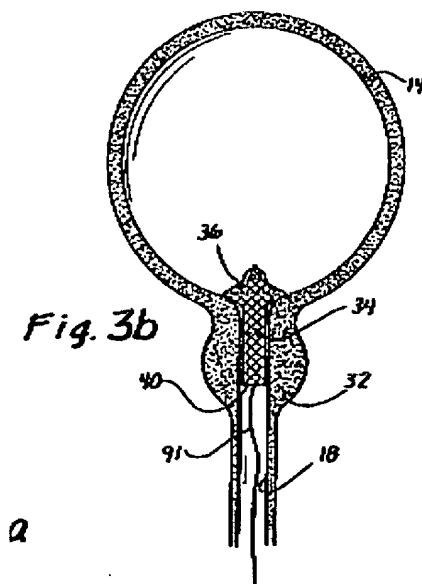
a stylet removably insertable into the elongate tube (34) so as to be able to facilitate insertion and placement of the catheter (10) in the body cavity (15)(page 11, lines 1-16)(see figure 1, *infra*).



Regarding claim 9, Pravong teaches means for deploying retention member (36)(page 11, lines 1-16).

Regarding claim 11, Pravong teaches a suture (91) and a collar (34) at a proximal end of the tube (see figure 3b, infra). Regarding the functional limitations of the claim, apparatus claims must be structurally distinguishable over the prior art. MPEP § 2114.

Regarding claim 12, Pravong teaches a end of the suture (91) attached to a handle (34) of a stylet.



Claims 1, 9, 11 and 12 are rejected under 35 U.S.C. § 102(d) as being barred by applicant's foreign patent to Pravong. See the rejection under 35 USC § 102(a), supra.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart as applied to claims 1-5 and 7-9 above, and further in view of Kasper *et al.* (US 4,148,319; hereinafter "Kasper").

Hart does not expressly disclose a plastic stylet.

Kasper discloses a catheter with a plastic stylet (12).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the plastic stylet material of Kasper in the catheter of Hart in order to provide a material that is known to be suitable for that purpose.

Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart as applied to claims 1-5 and 7-9 above, and further in view of Mickley.

Hart does not disclose a snap-fit connection.

Mickley teaches a snap-fit connection (23).

At the time of the invention, it would have been obvious to employ the snap-fit connection of Mickley to attach the inflation tube and catheter of Hart in order to provide a connection that is known in the art to be suitable for such purposes.

Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Mickley as applied to claims 15, 16 and 18-20 above, and further in view of Kasper.

Mickley does not expressly disclose a plastic stylet.

Kasper discloses a catheter with a plastic stylet (12).

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At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the plastic stylet material of Kasper in the catheter of Mickley in order to provide a material that is known to be suitable for that purpose.

Allowable Subject Matter

Claims 13 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
1 April 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

